

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BRISTOL MYERS SQUIBB :
COMPANY, :
 : Civil Action No. 23-3335(ZNQ)(JBD)
 :
Plaintiff, :
 :
v. : Hon. Zahid N. Quraishi
 : Hon. J. Brendan Day
XAVIER BECERRA, U.S. Secretary of :
Health & Human Services; *et al.*, :
 :
Defendants. :
 :
 :

**MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

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PRELIMINARY STATEMENT

Plaintiff Bristol Myers Squibb Company (BMS) is a New Jersey pharmaceutical company that manufactures life-saving medicines for serious diseases. Developing these medicines takes an extraordinary amount of time and money. Last year alone, BMS invested \$9.5 billion on research and development. One of BMS's flagship medicines is Eliquis, which doctors have prescribed to help millions of patients prevent deadly and life-altering blood clots and strokes. BMS invested billions of dollars in developing Eliquis before the medication ever could be given to patients, and much of the money earned on Eliquis sales is invested into further Eliquis research and into the discovery and development of future life-saving medicines. The Government now wants to force BMS to give Eliquis to Medicare for a fraction of its value—and, adding insult to injury, to “agree” that these forced transfers are “fair.” It will soon demand the same for other BMS medicines, including one that treats multiple cancers.

Those are the consequences of the so-called “Drug Price Negotiation Program” (the Program), part of the Inflation Reduction Act (IRA) enacted last summer. The Program's name suggests that Congress directed Government officials to negotiate with BMS and other pharmaceutical manufacturers over the prices the Government pays for their medicines through Medicare. But the Program involves neither true negotiations nor real agreements. It instead presents an “offer” that BMS cannot refuse: The IRA threatens ruinous financial penalties to *compel* BMS to provide third parties with “access” to Eliquis at whatever price the Government sets—and requires that price to be set far

below market value. It then misrepresents those forced transfers as the product of a negotiated agreement, to mislead the public into thinking that BMS has “agreed” that the Government-set discounted price is the “maximum fair price” for Eliquis.

This scheme is unconstitutional for at least two reasons.

First, the IRA takes BMS’s property without paying just compensation. The Fifth Amendment requires the Government to pay just compensation whenever it takes private property for public use. But the whole point of the Program is to take Eliquis for public use *without* paying its fair market value. It uses the threat of prohibitively high penalties to force BMS to transfer Eliquis to Medicare for a fraction of its market price. This is a classic *per se* taking.

Second, the IRA effects this taking by offending the First Amendment. Congress did not simply authorize Medicare to set maximum prices it will pay for covered drugs. Instead of straightforward price-setting, however, Congress enacted a convoluted Program that operates through faux “negotiations” and ends with requiring BMS to sign public “agreements” professing that the price the Government sets for Eliquis is its “maximum fair price.” Yet the First Amendment prohibits the Government from forcing companies to express the Government’s political message, especially when it does so to deceive the public or to conceal unpopular policies.

The Government cannot justify these constitutional violations by claiming BMS voluntarily waived its rights by participating in Medicare or Medicaid. The IRA imposes *mandates* backed by penalties, not *conditions* on participating in those programs. Even

viewed as a condition, the IRA’s draconian penalties and disproportionate threats leave BMS with only one genuine choice—to participate in faux “negotiations” and “agree” that the resulting Government-set, discounted price at which BMS will be required to provide Eliquis to Medicare is the medicine’s “maximum fair price.” The Program thus unlawfully coerces BMS to abandon its constitutional rights.

But the IRA’s worst consequences will fall on the American people. Pharmaceutical manufacturers like BMS develop medicines that save lives and improve the wellbeing of many millions of Americans. The average cost of bringing a new drug to market is more than \$2 billion. Stephen Ezell, *Ensuring U.S. Biopharmaceutical Competitiveness*, Info. Tech. & Innovation Found. 30 (July 2020), <https://www2.itif.org/2020-biopharma-competitiveness.pdf>. And for every successful treatment, many more ideas and experiments fail to produce a safe and efficacious treatment that reaches the market. Altogether, only a tiny fraction of research projects will recoup their development costs. Manufacturers thus depend on the profits from a small number of their most successful products to fund future research and development.

Yet the IRA targets precisely those products—the most successful medicines that are prescribed most often and dispensed to Medicare patients most frequently. The Program destroys those products’ revenue stream, cutting off the legs that support the entire endeavor. As a result, the IRA will skew pharmaceutical manufacturers’ ability to invest in potentially promising medicines—and so life-saving treatments for serious diseases like cancer, Alzheimer’s, and diabetes will never come to the market. *See Joe*

Grogan, *The Inflation Reduction Act is Already Killing Potential Cures*, WALL ST. J. (Nov. 3, 2022) (recounting cancellations of trials for new medicines due to IRA). Indeed, as a result of the IRA, BMS recently made the difficult decision not to pursue a registrational study of its drug iberdomide in newly diagnosed multiple myeloma patients. Decl. of Christopher T. Mancill (Mancill Decl.) ¶ 41.

Those consequences need never come to pass. The Court should declare that the IRA violates both the First and Fifth Amendments and enjoin Defendants from enforcing any coerced “agreement” against BMS.

BACKGROUND

A. The Government Dominates The Prescription Drug Market.

The federal Government “dominates” the U.S. prescription drug market, because it accounts “for almost half the annual nationwide spending on prescription drugs.” *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). Medicare is the largest federal drug benefit program, covering “nearly 60 million aged or disabled Americans.” *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019). Medicare operates two major prescription drug programs relevant to this case. Part B covers drugs administered by a physician., 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A), while Part D allows eligible individuals to enroll in privately operated plans for self-administered prescription drugs, with Medicare covering most of the premium costs, *see Action All. of Senior Citizens v. Leavitt*, 483 F.3d 852, 854 (D.C. Cir. 2007); Ryan Knox, Note, *More Prices, More Problems*, 18 YALE J. HEALTH POL’Y, L. & ETHICS 191, 205–06 (2019).

Both Medicare programs have historically used market-based pricing for prescription drugs. Part B reimbursement rates are based on an “average sales price” methodology. 42 U.S.C. § 1395w–3a. When it enacted Part D, Congress purposefully prohibited the Government from “interfer[ing] with the negotiations between drug manufacturers and pharmacies and [private plan sponsors].” *Id.* § 1395w–111(i). Plan sponsors “can and do negotiate prices with prescription drug manufacturers,” however, and have market incentives to secure lower prices. *Knox, supra*, at 206–07.

Medicaid is the second major federal drug benefit program providing health coverage to more than 70 million low-income Americans. *See id.* at 208–09. The States jointly administer Medicaid programs, which offer at least some prescription drug benefits for at least some classes of eligible beneficiaries. *See id.* at 209.

B. The IRA Requires That BMS “Agree” To Sell Its Medicines At Heavily Discounted Government-Set Prices, And Even Agree That Those Are Their “Maximum Fair Price[s].”

When Congress enacted the IRA in August 2022, it transformed how the Government will pay pharmaceutical manufacturers for their prescription medicines. By threatening prohibitively high penalties, the IRA pressures manufacturers to enter into “negotiations,” sign “agreements” that promise to transfer their medicines to Medicare beneficiaries at heavily discounted prices, and even “agree” these prices are the medicines’ “maximum fair price[s].”

To start, the Department of Health and Human Services (HHS) and its sub-agency, the Centers for Medicare & Medicaid Services (CMS), select drugs for the

Program. In September 2023, the agency will select ten drugs, for which “agreed” prices will take effect in 2026. *See* 42 U.S.C. §§ 1320f(d), 1320f–1(a)(1). Then, in February 2025 and February 2026, HHS will add fifteen new drugs for “agreed” prices effective beginning in 2027 and 2028 respectively. *Id.* § 1320f–1(a)(2)–(3). In February 2027 and later years, the agency must annually choose twenty new drugs to add to the Program. *Id.* § 1320f–1(a)(4). HHS must pick drugs based on their total cost to Medicare over the prior year. *Id.* § 1320f–1(b)(1)(A). Previously selected drugs remain in the Program until HHS determines that a generic or biosimilar version of the drug has been marketed. *Id.* § 1320f–1(c)(1).

In September 2023, after the agency selects the first ten drugs, manufacturers have until October 1 to “enter into agreements” to participate in the Program’s “negotiation” and to accept a “maximum fair price” (MFP) for selling their drug. *Id.* § 1320f–2(a). The agreement takes the form of a written contract that manufacturers must sign. Decl. of Toni-Ann Citera (Citera Decl.) Ex. A (CMS Revised Guidance) at 118. That contract contains the words “agree” and “fair” throughout. *See* Citera Decl. Ex. B (Template Agreement).

Next, the agency initiates the “negotiation” by issuing a “written initial offer” with a “concise justification.” 42 U.S.C. § 1320f–3(b)(2)(B). The IRA sets a ceiling that HHS may not exceed when it sets the price. It ranges from 75% of a benchmark market-based price (the non-federal average manufacturer price) for recently approved drugs, to 65% for a middle set, down to just 40% of that benchmark for drugs approved

for over 16 years. *Id.* § 1320f–3(b)(2)(F), (c)(1)(C). Thus, the Program mandates the Government be afforded a discount of *at least* 25%, 35%, or 60% from a market benchmark. And there is no floor on the price HHS may offer. The statute merely instructs the agency to consider certain factors in deciding how low of a price would be “fair.” *Id.* § 1320f–3(b)(2)(C)(ii), (e); *see also* Mancill Decl. ¶ 26. And the IRA purports to shield the agency’s pricing decisions from judicial review. *See* 42 U.S.C. § 1320f–7.

For the first round of drugs, these “negotiations” must end by August 1, 2024. *Id.* §§ 1320f(d)(5)(C), 1320f–3(b)(2)(E). That is when the manufacturer must “respond in writing” to the agency’s “final offer.” CMS Revised Guidance at 158. The manufacturer must “formalize agreement on an MFP” by signing an “Addendum” that “sets forth the agreed-upon MFP,” which the manufacturer must agree is the “maximum fair price” for its medicine. *Id.* at 159; *see also* Template Agreement at 7 (“Negotiated Maximum Fair Price Addendum”). HHS will “publish” to the public the MFP that it “negotiated with the manufacturer” with its “explanation” for the price it set. CMS Revised Guidance at 162–63; *see also* 42 U.S.C. § 1320f–4(a).

After signing this “agreement,” the manufacturer is required under its terms to provide “access to such price to” Medicare beneficiaries starting in 2026. 42 U.S.C. § 1320f–2(a)(1). Violations of that “access” commitment are punished by a monetary penalty of 10 times the difference between the price the manufacturer charges and the MFP, for each unit sold, *id.* § 1320f–6(a), plus a \$1 million daily penalty for violating the “agreement,” *id.* § 1320f–6(c).

Critically, none of these agreements are truly voluntary in any traditional sense of the word. Rather, the threat of draconian tax penalties coerces manufacturers into signing these “agreements.” By refusing to sign an initial agreement to “negotiate,” or by refusing to “agree” to the final MFP, a manufacturer starts incurring a daily “excise tax” beginning at 186% (and escalating to 1,900%) of the medicine’s total daily revenues from *all* sources (not just from Medicare). 26 U.S.C. § 5000D; Cong. Rsch. Serv., R47202, *Tax Provisions in the Inflation Reduction Act of 2022* 4 tbl. 2 (2022). These immense penalties—for BMS, reaching \$1 billion per day (*see* Mancill Decl. ¶ 24)—guarantee manufacturers will sign an “agreement”; that is evident from the fact that Congress projected this “tax” to raise “no revenue.” Joint Comm. On Tax’n, 117th Cong., Estimated Budget Effects of Revenue Provisions of Title XIII—Committee On Ways And Means, of H.R. 5376, Fiscal Years 2022–2031, at 8 (2021).

The only way a manufacturer could avoid the prohibitively high penalties while still refusing to sign an “agreement” is by terminating its contracts that provide for Medicare and Medicaid reimbursement—not just for the selected medicine but for *all* of that manufacturer’s products. The penalty is “suspend[ed]” only on days when a manufacturer is not a party to such an agreement for *any* of its products. 26 U.S.C. § 5000D(c). As such, a manufacturer could avoid the consequences of the Program *only* by losing access to half of the U.S. prescription drug market for *all* its products, meaning millions of Americans would be left without their medications.

But even that supposed “choice” is illusory. The IRA prohibits a manufacturer from ending Medicare Part D agreements for between 11 and 23 months. 42 U.S.C. § 1395w–114a(b)(4)(B). So, to avoid penalties for refusing to sign an initial agreement by October 1, 2023, a manufacturer would have had to terminate its contracts by January 31, 2022—well before the IRA was enacted. While CMS has recently attempted to provide an expedited exit option, it cannot rewrite the IRA. *See infra* at 32.

C. The Government Misrepresents The Program As Voluntary.

Despite the IRA’s mandates, the Government has publicly characterized the Program as creating a “negotiation” process resulting in “voluntary” “agreements.” When he signed the bill into law, the President touted that the IRA simply gave the Government “the power to negotiate lower prescription drug prices.” *Remarks by Pres. Biden on Medicare and the Inflation Reduction Act* (Sept. 27, 2022), <https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/09/27/remarks-by-president-biden-on-medicare-and-the-inflation-reduction-act/>. The President said the same thing at the 2023 State of the Union. *See Pres. Biden’s State of the Union Address* (Feb. 7, 2023), <https://www.whitehouse.gov/state-of-the-union-2023/>.

HHS and CMS have repeated these talking points, too. *See, e.g., CMS, Fact Sheet: The Inflation Reduction Act Lowers Health Care Costs for Millions of Americans* (Oct. 5, 2022). CMS has “note[d] that entering in an Agreement” “is voluntary” for manufacturers—even though they would have to pay enormous penalties were they to refuse to agree. *Citera Decl. Ex. C (CMS Initial Memo)* at 27; *see also CMS Revised Guidance* at 129.

D. BMS's Medicines Will Imminently Be Subject To The IRA.

BMS invests billions of dollars each year researching and developing new medicines that save lives. Mancill Decl. ¶¶ 3, 40. Yet only a few ideas result in FDA approval, let alone recoup their true development costs. Mancill Decl. ¶¶ 3, 40.

One of BMS's most successful medicines is Eliquis, which doctors prescribe to treat and prevent blood clots and strokes. Mancill Decl. ¶ 4. The Government will select Eliquis for the Program in September 2023. *See* Citra Decl. Ex. D, S. Dickson & I. Hernandez, *Drugs likely subject to Medicare Negotiation, 2026-2028*, 29 JMCP 229, 231 (Mar. 2023) (Dickson & Hernandez); Mancill Decl. ¶ 11. Opdivo, a BMS medicine that treats eleven different types of cancers, is projected to be swept up in a subsequent cycle of the Program. *See* Dickson & Hernandez at 232; Mancill Decl. ¶ 19.

The IRA will thus soon force BMS to make the Hobson's choice between signing a contract that will require it to pretend to "negotiate" a "fair" price for these medicines (for Eliquis, by October 1, 2023) or paying taxes that will exceed \$1 billion per day. *See* Mancill Decl. ¶ 24. In light of those penalties, BMS has no choice but to sign, even though BMS would not do so voluntarily. BMS will also have no choice but to "accept" the price the Government sets for Eliquis, despite BMS's belief that any such price—which will reflect at minimum a 25% discount from the benchmark price—will not be "fair." Mancill Decl. ¶ 26. And as a result, BMS will be forced to provide Medicare with "access" to its medicines at steep discounts—and convey the misimpression that it did so voluntarily. *See* Mancill Decl. ¶¶ 24, 26, 34.

LEGAL STANDARD

A “court shall grant summary judgment” if there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a), (c). Constitutional challenges to federal statutes are often resolved on summary judgment. *See, e.g., Const. Party of Pa. v. Cortes*, 824 F.3d 386, 393, 399 (3d Cir. 2016). Where, as here, a plaintiff requests declaratory relief, “[t]he court may order a speedy hearing of a declaratory-judgment action.” Fed. R. Civ. P. 57.

ARGUMENT

The IRA forces BMS to transfer its most successful medicines to Medicare at well below market prices—and compels BMS to publicly “agree” that this scheme is “fair.” The Court should declare this Program unconstitutional—and enjoin the Government from enforcing any “agreement” against BMS—to protect the American people from a crippling loss of innovation if the Program takes full effect.

Under the Takings Clause, the Government must pay fair market value if it takes private property for public use. *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063 (2021); *Horne v. Dep’t of Agric.*, 576 U.S. 351 (2015). Here, that means the Government cannot appropriate BMS’s medicines for the benefit of Medicare beneficiaries while paying less than fair market value. Dictating a massive discount by legislative fiat is a transparent violation of the Fifth Amendment. Declaratory relief is appropriate, to assure BMS—and caution the Government—that the Government *will* have to pay just compensation if it proceeds with forced seizures of Eliquis and other medicines.

Moreover, the means by which the Government will effectuate this taking violate the First Amendment. It is well-settled that the Government cannot compel businesses to communicate messages against their will. *Nat'l Inst. of Fam. & Life Advoc. v. Becerra*, 138 S. Ct. 2361, 2371 (2018); *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps.*, 138 S. Ct. 2448, 2463–64 (2018). But the IRA forces BMS to communicate the Government's viewpoint by pretending to “negotiate” and “agree” that the heavily-discounted, Government-set prices are the “maximum fair price[s]” for its medicines. This facade—designed to cover up an unconstitutional taking—strikes at the heart of the First Amendment. The Court should therefore permanently enjoin it.

I. THE IRA VIOLATES THE FIFTH AMENDMENT BY TAKING BMS'S PRIVATE PROPERTY WITHOUT JUST COMPENSATION.

The IRA effects a taking of BMS's medicines without paying just compensation. Eliquis is BMS's private property. The Government has promised to give Medicare beneficiaries access to Eliquis, but it does not want to pay fair market value. The IRA's solution is to coerce BMS to transfer Eliquis to Medicare at a cut-rate price. But a Government-imposed 50% discount on forced transfers of Eliquis is no different than if the Government were to seize 50% of BMS's inventory. Either way, the Government is taking BMS's private property without paying the just compensation—meaning fair market value—that is required by the Fifth Amendment. Declaratory relief is warranted to clarify BMS's rights and the Government's obligations as well as to protect the innovation necessary to develop the next generation of life-saving medicines.

A. The Fifth Amendment Prohibits The Government From Taking Personal Property Without Paying Just Compensation.

The Fifth Amendment's Takings Clause provides: "[N]or shall private property be taken for public use, without just compensation." U.S. CONST. amend. V. This provision "bar[s] Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole." *Armstrong v. United States*, 364 U.S. 40, 49 (1960). It establishes a "simple, *per se* rule: The government must pay for what it takes." *Cedar Point*, 141 S. Ct. at 2071.

The Takings Clause fully applies to personal property. The Government "has a categorical duty to pay just compensation" when it "appropriate[s] personal property." *Horne*, 576 U.S. at 358. A "classic" or *per se* taking occurs when the Government forces a property owner to transfer possession or title, whether to "itself or someone else," *Cedar Point*, 141 S. Ct. at 2072, because the owner loses the "rights to possess, use and dispose of" his property, *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982). In *Horne*, for example, the Supreme Court found a taking of "personal property" where a statute directed farmers to "turn over a percentage of their raisin crop without charge," under pain of penalties. 576 U.S. at 358, 361–62.

A forced transfer dressed up as a "sale" is equally a taking of private property. Whenever the Government forces a "sale" of private property from one person to another, a taking occurs. *See, e.g., Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993) (explaining that where businesses "are compelled to employ their property to provide

services to the public, the Fifth Amendment requires” payment of just compensation). The forced sale may nonetheless satisfy the Fifth Amendment if the imposed “price” constitutes just compensation, meaning “the market value of the property,” *Horne*, 576 U.S. at 368–69—but there is a taking regardless, *see id.* at 363–64 (prospect that farmers would receive proceeds from government resale of their appropriated raisins affected only the question of compensation, but did not erase the taking).

Notably, a forced transfer of property is not the same as a price cap. The latter *forbids* sales on certain terms but does not *compel* sales on any terms, and it leaves open other means of using the property in question. *See, e.g., Yee v. City of Escondido*, 503 U.S. 519, 527–28 (1992) (rent-control law that does not “compel[]” owners “to continue” renting would not be a taking, since the owner has a “voluntar[y]” choice about how to *use* the property, including by living in it, selling it, etc.); *see also Bowles v. Willingham*, 321 U.S. 503, 517 (1944) (rent-control law had “no requirement that the apartments ... be used for the purposes which bring them under the Act”). A forced transfer is different because it leaves the property owner with no choice but to surrender title and submit to the “appropriation” of private property. *Horne*, 576 U.S. at 362.

B. The IRA Effects A Taking Of BMS’s Private Property Without Paying Just Compensation For Its Medicines.

The IRA flouts these constitutional principles by taking BMS’s patented medicines for the benefit of Medicare beneficiaries. The whole point of this scheme is for the Government to avoid paying just compensation by paying far less than the fair

market price for Eliquis. The Court should declare that this forced transfer of BMS's private property violates the Fifth Amendment's Takings Clause.

1. Eliquis is private property protected by the Takings Clause.

As a threshold matter, patented medicines are protected by the Takings Clause. Eliquis is private property no less than raisins and cars. *See Horne*, 576 U.S. at 358; *United States v. Gen. Motors*, 323 U.S. 373, 383–84 (1945). In addition, these medicines are covered by patents “confer[ring] upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation.” *Horne*, 576 U.S. at 359; *see also Oil States Energy Servs., LLC v. Greene’s Energy Grp.*, 138 S. Ct. 1365, 1375 (2018) (explaining that patents “are entitled to protection as any other property”); *Hartford-Empire Co. v. United States*, 323 U.S. 386, 415 (1945) (“That a patent is property, protected against appropriation by both individuals and by government, has long been settled.”).

2. The IRA’s compelled sales regime is a *per se* taking.

The IRA’s compelled “sales” regime will effect a *per se* taking of BMS’s private property. After the Government selects Eliquis for inclusion in the Program, BMS must “agree” to “negotiate” a price for Eliquis and ultimately “accept” the agency’s final price—backed by the threat of ruinous financial penalties if BMS balks. *See* 26 U.S.C. § 5000D (penalty for failure to agree to negotiate or to the MFP). Then, the IRA and these coerced “agreements” will require BMS to provide “access” to Eliquis at the MFP to Medicare beneficiaries and those who buy it on their behalf. 42 U.S.C. § 1320f–

2(a)(3). This statutory “access” mandate forces BMS to transfer Eliquis to those third parties at the price demanded by the Government—BMS cannot refuse to deal on those terms. This “requires physical surrender of [Eliquis] and transfer of title,” and BMS “lose[s] any right to control [its] disposition.” *Horne*, 576 U.S. at 364. That effectuates a classic, *per se* taking. *See id.* at 362; *Cedar Point*, 141 S. Ct. at 2072.

The IRA’s scheme of compulsory sales operates differently than a mere price cap. This is not a situation where the statute merely sets a maximum price the Government will pay for Eliquis, if BMS “voluntarily” chooses “to continue” selling to Medicare beneficiaries. *Yee*, 503 U.S. at 527–28. Those types of mandates might be “regulation,” not “appropriation,” *Horne*, 576 U.S. at 362, but they would create the risk that Medicare beneficiaries might be unable to access their medications if BMS chose not to sell its product at the Government-set price. To prevent BMS from refusing to deal with the Government on the Government’s terms, the Program *mandates* “access.” *Cf. Cedar Point*, 141 S. Ct. at 2072 (holding that law granting union “access” to property was *per se* taking). In turn, this requirement that BMS use its “property to provide [medicines] to the public” triggers the Fifth Amendment’s requirement to pay just compensation. *Garelick*, 987 F.2d at 916.

The fact that the IRA launders these forced transfers through an “agreement” is immaterial because the statute contains draconian penalty provisions that compel BMS to sign the “agreement.” *See, e.g., Murdock v. Pennsylvania*, 319 U.S. 105, 113–14 (1943) (holding that taxes “for the enjoyment of a right granted by the Federal Constitution”

are “a restriction of the free exercise of those freedoms”); *E. Enters. v. Apfel*, 524 U.S. 498, 529 (1998) (plurality op.) (Coal Act effected taking by using “severe penalty” to coerce monetary exactions); *Horne*, 576 U.S. at 356 (demand for raisins enforced through penalties was a taking). Allowing the Government to circumvent the Takings Clause by forcing owners to make the illusory choice between “agreeing” to forfeit their property or paying crippling penalties would effectively write the clause out of the Constitution.

3. The IRA intentionally provides less than market value for the Government’s taking of BMS’s property.

Because it effects a taking, the IRA triggers the Government’s obligation to pay just compensation—namely, “fair market value” of BMS’s property. *United States v. Reynolds*, 397 U.S. 14, 16 (1970); *see also United States v. 564.54 Acres of Land*, 441 U.S. 506, 511 n.6 (1979) (“value of [merchandise]” in takings case “is ordinarily what it can command in the marketplace”). But the statute is written precisely to *prevent* the Government from paying fair market value for Eliquis. In fact, the statute sets the ceiling price at no more than 75% of the average price paid by non-federal purchasers in the market. 42 U.S.C. § 1320f–3(b)(2)(F), (c)(1)(C). But the Government can also demand even steeper discounts for Eliquis in its purportedly unreviewable discretion. *Id.* § 1320f–7. By definition, then, the IRA does not provide just compensation for the taking of BMS’s private property, because the statute mandates prices that deliberately fall far below fair market value. *See Horne*, 576 U.S. at 368–69.

But this Court need not determine the fair market value of Eliquis (or any other medicine) to grant relief to BMS in this case. BMS is not seeking damages here, so the remedial question of how to calculate them is beyond the scope of this facial challenge. *See Horne*, 576 U.S. at 364 (distinguishing these questions). The only relief that BMS seeks from this Court on its takings claim is a declaration that the IRA mandates a taking without paying just compensation. And all the Court needs to recognize, to grant that relief, is that 75% or less of a market price is not just compensation. The market value of X cannot be a mere fraction of X's market value.

At bottom, *Horne* is controlling here. Like the IRA, the statute in *Horne* used penalties to coerce owners to turn over their property, *see* 576 U.S. at 362, triggering Government's "categorical duty to pay just compensation," *id.* at 358. The Government in *Horne* took a portion of a farmer's raisins, while here the Government is taking BMS's medicines for a fraction of their value, but these two appropriations are materially indistinguishable. Seizing 50% of a company's inventory has the same effect as seizing that inventory at a 50% discount. The Government's partial payments for Eliquis are relevant only to the amount of just compensation, just as with the partial proceeds that the farmers would get from the resale of their raisins seized by the Government. *See id.* at 364. Those partial payments do not eliminate the taking. *See id.* Accordingly, "[t]he government must pay for what it takes." *Cedar Point*, 141 S. Ct. at 2071.

C. The Court Should Enter Declaratory Relief.

The appropriate remedy in this case is to declare that the IRA effects a taking of BMS's private property without paying just compensation. The Declaratory Judgment Act permits declaratory relief when "appropriate." 28 U.S.C. § 2201. That relief is appropriate if a declaration would "resolve the uncertainty" that "gave rise to the controversy"; promote "the convenience of the parties," especially relative to "other remedies" that may be available; and further "the public interest." *Reifer v. Westport Ins. Corp.*, 751 F.3d 129, 140 (3d Cir. 2014). Those criteria are satisfied in this case.

First, declaratory relief would resolve uncertainty about the constitutionality of the IRA—in particular, whether the Government must pay compensation for taking BMS's property. The Supreme Court has long permitted litigants to seek declaratory relief against threatened statutory takings when the law does not provide "advance assurance of adequate compensation in the event of a taking." *Duke Power Co. v. Carolina Envt'l Study Grp.*, 438 U.S. 59, 71 n.15 (1978); *see also Carteret Sav. Bank, F.A. v. Office of Thrift Supervision*, 963 F.2d 567, 584 (3d Cir. 1992) (citing *Duke Power* on this point). The IRA fits the bill because it takes BMS's property but provides only partial, below-market compensation.

Second, a declaration would promote the convenience of the parties, because it will inform whether BMS will be able to bring an after-the-fact suit for compensation against the Government—a matter that has considerable immediate importance for both parties and should not be left in limbo for years to come.

The question in this case is whether the IRA effects an unconstitutional taking, but the amount of just compensation would be decided in the Court of Federal Claims only after those takings occur in 2026 and beyond. Leaving the constitutional question unresolved until after the Government begins to compel the sale of Eliquis creates untenable uncertainty for both parties. BMS needs to know how the IRA will impact pharmaceutical pricing, so it can plan its research and development. *See* Mancill Decl. ¶ 42. The Government also needs to know now whether below-market MFPs will expose the Treasury to monetary judgments in the Court of Federal Claims, because every dollar of discounts the Government takes now will “generate a dollar of ... compensation” later (plus interest). *E. Enters.*, 524 U.S. at 521, 530 (plurality op.) (finding that declaratory relief was “appropriate” because deferring takings issue until after-the-fact suits for damages would be “utterly pointless” given that “every dollar paid” into the fund would “generate a dollar of ... compensation” later).

Third, the public interest would be served by adjudicating this takings issue now. As noted, the IRA is *already* deterring the potential discovery of the next generation of life-saving therapies, which need enormous investments in research and development that manufacturers may no longer be able to justify. *See* Mancill Decl. ¶ 41 (recounting how BMS recently decided not to pursue certain multiple myeloma research for one of its medicines as a result of IRA); Grogan, *supra*. The longer this new regime is in place, the greater the loss of medical progress—and the more the public will suffer as a result. Worse, these effects will be most acute with cancer and other serious diseases in search

of a cure. *See* Mancill Decl. ¶ 42. A declaratory judgment will help restore order to a scientific landscape that has been roiled by the IRA’s passage. And if the Court concludes that the IRA is unconstitutional, Congress should have an opportunity to consider other means to accomplish its cost-saving objectives in a constitutional manner sooner rather than later.

For all of these reasons, the Court should enter a declaratory judgment that the IRA violates the Fifth Amendment’s Takings Clause.

II. THE IRA VIOLATES THE FIRST AMENDMENT BY COMPELLING BMS TO EXPRESS THE GOVERNMENT’S POLITICAL MESSAGES.

But the taking of BMS’s property is just the beginning. The IRA also infringes on First Amendment rights by forcing BMS to pretend to engage in sham “negotiations” resulting in faux “agreements” that require BMS to publicly express the Government’s view that the forced transfer of BMS’s medicines at below-market prices is “fair.” Congress could have obtained lower prices for Eliquis by simply setting a maximum price the Government would pay, but that would have been too transparent. Instead, Congress ordered BMS to “agree” to the forced transfer of its medicines at heavily-discounted prices and to convey that it agrees those discounted prices are the “maximum fair price[s].” The First Amendment forbids the Government to conscript BMS to express this political message. This Court should therefore enjoin the “agreement” obligation.

A. The Government Cannot Force Private Parties To Communicate Its Political Messages.

“[T]he First Amendment guarantees ‘freedom of speech,’ a term necessarily comprising the decision of both what to say and what *not* to say.” *Riley v. Nat’l Fed’n of the Blind*, 487 U.S. 781, 796–97 (1988). The Government thus can neither “prohibit the dissemination of ideas that it disfavors, nor compel the endorsement of ideas that it approves.” *Knox v. Serv. Emps. Int’l Union, Local 1000*, 567 U.S. 298, 309 (2012); *see also Hurley v. Irish-American Gay, Lesbian & Bisexual Grp. of Boston, Inc.*, 515 U.S. 557, 573 (1995). Just a few weeks ago, the Supreme Court reiterated in robust terms that the Government cannot “compel a person to speak its own preferred messages.” *303 Creative LLC v. Elenis*, 143 S. Ct. 2298, 2312 (2023).

These principles protect businesses as well as individuals. “For corporations as for individuals, the choice to speak includes within it the choice of what not to say.” *Pac. Gas & Elec. Co. v. Pub. Utils. Comm’n*, 475 U.S. 1, 16 (1986) (plurality op.). The Government thus cannot force a business to serve as a “vehicle for spreading a message with which it disagrees.” *Id.* at 17; *see also, e.g., United States v. United Foods, Inc.*, 533 U.S. 405, 411 (2001) (mushroom growers could not be forced to promote the general sale of all mushrooms). After all, “the First Amendment extends to all persons ... including those who seek profit,” and speakers do not “shed their First Amendment protections by employing the corporate form.” *303 Creative*, 143 S. Ct. at 2316, 2320.

Put simply, the Government cannot “compel speakers”—regardless of their identity—“to utter or distribute speech bearing a particular message.” *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 642 (1994). Laws that compel speech are subject to strict scrutiny, *see id.*, which requires the Government to show the law is “narrowly tailored” to achieve a “compelling” government interest, *Pac. Gas*, 475 U.S. at 19 (plurality op.).

B. The IRA Compels BMS To Express “Agreement” That There Is A “Negotiation” And That The Government-Mandated Price For Eliquis Is Its “Maximum Fair Price.”

The IRA infringes BMS’s First Amendment rights by forcing it to communicate the Government’s viewpoint or else pay crippling penalties. BMS is literally required to express its public “agreement” both to engage in faux “negotiations” and with the “fair[ness]” of the Government-dictated price for Eliquis. This scheme serves no legitimate purpose; it is designed solely to facilitate the political misimpression that BMS “agrees” with these mandates.

1. The IRA compels BMS to convey the Government’s preferred viewpoint.

The IRA “coerc[es]” BMS to express the Government’s viewpoint by using the “threat of punishment,” including “monetary fines.” *303 Creative*, 143 S. Ct. at 2313. This happens in two steps. *First*, BMS must “enter into” a public “agreement” with the Government, 42 U.S.C. § 1320f–2(a), promising to “negotiate” a “maximum fair price” for its medicines, Template Agreement at 1. *Second*, when the pretend “negotiation” process concludes, BMS must publicly “agree to” the final “maximum fair price” HHS

offers, 42 U.S.C. § 1320f–2(a)(1), by signing a “Negotiated Maximum Fair Price Addendum,” Template Agreement at 7; 42 U.S.C. § 1320f–4(a); CMS Revised Guidance at 162–63. The IRA coerces BMS by threatening sanctions unless it signs on the dotted line. Every day that BMS balks at signing either “agreement” counts as “noncompliance” and triggers crippling penalties. 26 U.S.C. § 5000D.

BMS’s signature communicates to the public (1) that it is willingly entering into *bona fide* negotiations with the Government over the price of Eliquis; (2) that these “voluntary” negotiations will culminate in a mutually agreed-upon price for Eliquis; and (3) that the final price the Government sets is the “maximum fair price” for Eliquis. For example, the Template Agreement recites that the parties will “negotiate to determine a price,” and that the manufacturer contemplates reaching “agreement with CMS.” Template Agreement at 1. It goes on to use the terms “agree,” “agreement,” and “maximum fair price” dozens of times. *See id.* at 1–5. The Addendum BMS must sign at the second step communicates that the parties “negotiated” a price they agree is the “maximum fair” one, and repeats that the parties “engaged in negotiation” and “agree” to the Government’s price. *Id.* at 7.

Yet BMS does *not* voluntarily “agree” with any of this. BMS disagrees that the Program involves a real “negotiation” because BMS has zero leverage and would face unconscionable punishment were it to walk away. BMS disagrees that its participation in the Program is voluntary because the Government’s threat of massive penalties coerces BMS to sign up and participate. BMS also disagrees that the Government-

dictated price for Eliquis will be the “maximum fair price” for its medicine. BMS instead believes that drastically discounting the price of Eliquis (and more of its medicines to come) will harm the public by undermining and skewing its investment in and ability to develop new life-saving medications. *See* Mancill Decl. ¶ 25.

To be sure, many contracts do not express views or convey beliefs. But some transactions can be expressive. *See, e.g., 303 Creative*, 143 S. Ct. at 2312 (forcing business to create website); *New Hope Fam. Servs., Inc. v. Poole*, 966 F.3d 145, 177–78 (2d Cir. 2020) (forcing adoption agency to “approve” adoption for same-sex couple). The compelled speech is doubly problematic here, because the IRA forces BMS to both *transact* (and thus *imply* agreement) and explicitly “*agree*” in writing that the Government’s below-market dictated price is the “maximum fair price” for its medicine.

Indeed, the misimpression that BMS endorses the Government’s viewpoint is the Program’s central feature. Instead of ordering the Government to set a maximum price for Eliquis, the IRA conceals the Government’s price-setting and forced sales by laundering its mandates through “agreements,” so it appears as if BMS is choosing to give the Government a massive break on the price of Eliquis.

This regime violates the two core purposes of the compelled speech doctrine. *First*, the doctrine prevents the Government from forcing citizens to act contrary to their beliefs. “At the heart of the First Amendment lies the principle that each person should decide for himself or herself the ideas and beliefs deserving of expression, consideration, and adherence.” *Turner Broad.*, 512 U.S. at 641. Indeed, its “very purpose

... is to foreclose public authority from assuming a guardianship of the public mind.” *Thomas v. Collins*, 323 U.S. 516, 545 (1945) (Jackson, J., concurring); accord *Wooley v. Maynard*, 430 U.S. 705, 714 (1977). When the Government compels one to spread a message that person rejects, it “invades the sphere of intellect and spirit” that must lie beyond “official control.” *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943). This type of coercion is contrary to a “political system” built on free expression, *Turner*, 512 U.S. at 641, in which all enjoy the “right to present their message undiluted by views they d[o] not share,” *303 Creative*, 143 S. Ct. at 2311.

Here, however, by forcing BMS to “agree” that the Government-dictated price is “fair,” the IRA compels BMS to express the Government’s political viewpoint—one that BMS vehemently rejects. Again, BMS believes drug prices should be set to encourage innovation and allow this life-saving industry to flourish. See Mancill Decl. ¶¶ 25, 32. Yet the IRA compels BMS to affirmatively espouse the Government’s counternarrative: that BMS would charge *more* than a “fair” price for Eliquis if not for the IRA’s mandated “negotiations.” This type of Government coercion violates the First Amendment’s basic guarantee of “freedom of mind.” *Wooley*, 430 U.S. at 714.¹

¹ In cases involving some purely factual and uncontroversial commercial disclosures, the Supreme Court has endorsed a slightly relaxed level of scrutiny. See, e.g., *Zauderer v. Off. of Disciplinary Couns. of Supreme Ct. of Ohio*, 471 U.S. 626, 651 (1985); see also *Nat’l Inst.*, 138 S. Ct. at 2372, 2377–78. That standard is inapt in this case because the IRA’s compelled speech is neither purely factual nor uncontroversial—to the contrary, it touches fundamental and hotly contested questions about whether market-driven prices are “fair.”

Second, the compelled speech doctrine preserves an “open marketplace in which differing ideas about political, economic, and social issues can compete freely for public acceptance without improper government interference.” *Knox*, 567 U.S. at 309. “[F]reedom of thought and speech is ‘indispensable to the discovery and spread of political truth.’” *303 Creative*, 143 S. Ct. at 2311. But when the Government “requires the utterance of a particular message favored by the Government,” it “manipulate[s] the public debate through coercion rather than persuasion.” *Turner*, 512 U.S. at 641. This can corrupt “the processes through which political discourse or public opinion is formed.” *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 49 (2017) (Breyer, J., concurring). To prevent such distortion, the Supreme Court has held that speakers cannot be forced to express “agree[ment] with the Government’s polic[ies].” *Agency for Int’l Dev. v. All. for Open Soc’y Int’l, Inc.*, 570 U.S. 205, 213 (2013).

Yet again, the IRA’s “negotiated agreements” do exactly that and distort public debate over the Program. By forcing BMS to present itself as a willing party, the IRA enhances—and insulates from criticism—the position that the Government’s price for Eliquis is the “maximum fair price” and has been “agree[d] to” by BMS. 42 U.S.C. § 1320f–2(a)(1). To be sure, BMS remains free to protest using counterspeech, but the Government cannot “require speakers to affirm in one breath that which they deny in the next.” *Pac. Gas*, 475 U.S. at 15 n.11 & 16 (plurality op.); *Hurley*, 515 U.S. at 576. The Government may want the public to believe that the price for Eliquis would be “unfair” if not for the IRA, but it cannot compel BMS to agree to that proposition.

2. A disclaimer cannot cure the constitutional harm.

After this lawsuit was filed, the Government tried to mitigate these First Amendment problems by allowing manufacturers to include a misleading disclaimer in their “agreement.” That language purports to say that the agreement does not reflect an “endorsement of CMS’ views” or that “fair” means “fair” in the “colloquial” sense. Template Agreement at 4. Instead, the manufacturer is supposedly only agreeing on a “maximum fair price” as those words are “specified in the statute.” *Id.*

But the Government’s decision to add that disclaimer only underscores the implication that is otherwise apparent. And a “disclaimer ... does not suffice” to cure these First Amendment problems for the same reason that counterspeech does not cure them: The Government cannot “require speakers to affirm in one breath that which they deny in the next.” *Pac. Gas*, 475 U.S. at 15 n.11 & 16 (plurality op.).

The Third Circuit so held in *Circle Schools v. Pappert*, 381 F.3d 172 (3d Cir. 2004), in which private schools challenged a state law mandating recital of the Pledge of Allegiance. The Third Circuit rejected the State’s defense that any objecting school could “make a general disclaimer regarding the recitation”: “[T]he fact that the schools can issue a general disclaimer along with the recitation does not erase the First Amendment infringement at issue here, for the schools are still compelled to speak the Commonwealth’s message.” *Id.* at 182. “Otherwise,” the court explained, government could “infringe on anyone’s First Amendment interest at will, so long as the mechanism of such infringement allows the speaker to issue a general disclaimer.” *Id.*

“So too would a disclaimer here be inadequate.” *Telescope Media Grp. v. Lucero*, 936 F.3d 740, 757 (8th Cir. 2019). By forcing BMS to sign agreements committing to “negotiate,” purporting to “agree,” and communicating that an HHS-dictated price for Eliquis is “fair,” the IRA compels BMS to express viewpoints it rejects. No disclaimer can change that BMS’s “own message” will already be “affected by the speech it was forced to accommodate.” *Rumsfeld v. FAIR*, 547 U.S. 47, 63 (2006).

3. The IRA cannot satisfy heightened scrutiny.

Because the IRA compels BMS “to embrace a certain viewpoint,” it must satisfy strict scrutiny. *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 188 (3d Cir. 2005). But the Program cannot survive any level of scrutiny because its burdens on protected speech do not advance any legitimate interest—much less a compelling one. Instead of authorizing HHS to set maximum prices, Congress chose faux “negotiations” and “agreements” to conceal the IRA’s price-setting and forced transfers. Forcing BMS to carry the Government’s deceptive messages does nothing to reduce drug prices for Medicare beneficiaries. But it does add political cover. While the public supports *negotiating* drug prices, it does not support governmental *price-setting*, especially in the health-care arena. *See* National Tracking Poll #2109099, Morning Consult, at 13, 17 (Sept. 16-19, 2021) (showing steep decline in support when asked about price-setting). Congress thus cloaked the IRA’s price-setting mandates with faux “agreements” to mislead the public about how the Program operates. If this kind of political deception could justify compelled speech, the First Amendment would be a dead letter.

C. The Court Should Enjoin The Program.

The Court should remedy this First Amendment violation with an injunction preventing the Government from forcing BMS to sign any agreement or enforcing any such coerced agreement. “The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.” *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality op.). The Supreme Court thus regularly finds injunctive relief to be appropriate in compelled speech cases. *See, e.g., Nat’l Inst.*, 138 S. Ct. at 2370; *Riley*, 487 U.S. at 787, 803; *Wooley*, 430 U.S. at 712, 717.

The equities and public interest also support awarding injunctive relief. The Government has no legitimate justification for compelling BMS to express its political viewpoints. Its interest is no different from the public interest—and the public will lose out from systematic manipulation of the marketplace of ideas, not to mention from the loss of medical innovation associated with the IRA’s forced transfers. *Supra* at 20-21.

Thus, the Court should declare that the IRA’s requirements to “agree” to “negotiate” and to accept “maximum fair prices” are unconstitutional and enjoin the Government from enforcing them. In particular, it should enjoin Defendants from compelling BMS to sign an initial “manufacturer agreement,” 42 U.S.C. § 1320f–2(a), or to “agree to” the “maximum fair price” developed through the Program, *see id.* § 1320f–2(a)(1), (a)(2). If BMS signs any agreement before the Court issues its decision in this case, the Court should also declare those agreements void and enjoin Defendants from enforcing their terms against BMS.

III. BMS DID NOT SURRENDER ITS CONSTITUTIONAL RIGHTS BY PARTICIPATING IN MEDICARE AND MEDICAID.

The Government cannot excuse these two constitutional problems by claiming BMS voluntarily submitted to the IRA’s mandates—and thus surrendered its constitutional rights—by accepting Medicare or Medicaid coverage for Eliquis and its other medicines. BMS cannot be forced to choose between complying with unconstitutional Government mandates backed by crippling penalties or destroying its business by cutting off almost half of all patients in the United States. No matter how the choice is framed, it is unconstitutional.

A. The IRA Does Not Impose A Mere Condition On Participating In Medicare And Medicaid.

At the outset, although the Government sometimes attaches conditions on receiving public benefits, the IRA’s mandates do not take the form of a condition. When Congress attaches conditions on federal funds, it explicitly ties its mandates to the funds. *See, e.g.*, 42 U.S.C. § 2000d (prohibiting race discrimination in any “program or activity receiving Federal financial assistance”); 29 U.S.C. § 794(a) (same for disability discrimination); 42 U.S.C. § 300a–6 (“None of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning.”).

But the IRA does not expressly tie its mandates to the receipt of federal funds; it applies to manufacturers of any drugs that HHS selects. *See* 42 U.S.C. § 1320f(a). Nor do manufacturers have any choice in the matter; the IRA’s requirements use the mandatory word “shall.” *See, e.g., id.* § 1320f–3(a); *id.* § 1320f–2(a)(3). And the

Government enforces those requirements with penalties for “noncompliance,” 26 U.S.C. § 5000D, not by withholding Medicare payments, *compare, e.g.*, 42 U.S.C. § 1396r–8(a). In short, these are not conditions—these are mandates.

Indeed, participation in Medicare or Medicaid is irrelevant until the back-end penalty calculation. At that point, the IRA’s penalties can be suspended if *none* of BMS’s medicines are covered by a Medicare or Medicaid coverage agreement. Even that “choice” is illusory, however. Under the IRA, BMS cannot extricate itself from these programs without giving notice at least 11 and as many as 23 months in advance of termination. 42 U.S.C. § 1395w–114a(b)(4)(B)(ii). Accordingly, the only way BMS could have pulled all of its medicines from Medicare by October 1, 2023—the first deadline by which it must “agree” or face daily penalties—would have been to give notice of this intent by January 31, 2022, which was months before the IRA’s enactment. Avoiding the IRA’s mandate would thus have been impossible.

After this suit was filed, CMS announced a supposed administrative “fix” for this problem. While the statute requires *manufacturers* to provide up to 23 months’ notice to withdraw, it lets *CMS* terminate a manufacturer for “willful violation ... or other good cause” on a shorter timeframe (30 days). 42 U.S.C. § 1395w–114a(b)(4)(B)(i). CMS now says it will exercise that power to help any manufacturer who wishes to avoid the Program without waiting the 11–23 months that Congress required. *See* Revised Guidance at 120–21, 130–31. But of course, the agency cannot override Congress’s text, and Congress spoke directly to the question of how a manufacturer can initiate

exit from these programs. More importantly, this end-run only underscores that *Congress* never intended to give manufacturers a genuine choice—proving again that the IRA imposes mandates, not conditions that could be “voluntarily” accepted.

B. Even If Framed As A Condition, The IRA’s Mandates Are Unconstitutionally Coercive And Disproportionate.

In any event, characterizing the IRA’s mandates as a “condition” would not cure the law’s constitutional violations. *See Horne*, 576 U.S. at 366 (rejecting argument that raisin appropriation was a “condition” on “a Government benefit” because it could not “reasonably be characterized as part of a ... voluntary exchange”); *Cedar Point*, 141 S. Ct. at 2080 (rejecting argument that Government could “require property owners to cede a right of access as a condition of receiving certain benefits” because union access rule was not “germane to any benefit provided to [the property owners] or any risk posed to the public”); *Agency for Int’l Dev.*, 570 U.S. at 218–19 (rejecting argument that speech compulsion was “a condition on the receipt of [federal funds]” because a condition cannot be used to require “recipients to profess a specific belief”).

Under a long line of Supreme Court precedent, the IRA’s mandates are both unconstitutionally coercive (because they do not offer a genuine choice to which any manufacturer could “voluntarily” agree) and impermissibly compel the surrender of constitutional rights (because they are neither germane nor proportionate to the federal benefits they leverage).

1. The IRA's mandates are coercive.

Although Congress has some leeway to attach conditions on the receipt of federal funds, recipients must “voluntarily ... accept” Congress’s “terms.” *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). But such conditions become unconstitutional when “persuasion gives way to coercion.” *Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 585 (2012) (*NFIB*). Congress must offer a *genuine* choice that a recipient can voluntarily accept; that choice cannot be “illusory,” *United States v. Butler*, 297 U.S. 1, 71 (1936), and must exist “not merely in theory but in fact,” *NFIB*, 567 U.S. at 581.

NFIB illustrates a federal funding condition that was unconstitutionally coercive. The Court held that Congress could not force a State to expand Medicaid coverage by “threatening to withhold all of [its] Medicaid grants.” 567 U.S. at 575. Three features rendered that condition unconstitutional. *First*, Congress “threaten[ed] to withhold ... existing Medicaid funds” from States that do not accept those “new conditions,” *id.* at 579, which showed that the Government was using its power as a “means of pressuring” recipients. *Id.* at 575–76, 580. *Second*, the pressure was unconstitutionally coercive because it threatened about 10% of a State’s budget. *Id.* at 581–82. *Third*, Congress upset reliance interests developed after “many decades” by imposing “post-acceptance retroactive conditions” that States “could hardly [have] anticipate[d].” *Id.* at 581, 583–84. In sum, the Court rejected the Government’s attempt to leverage large,

pre-existing funding streams which recipients had relied on and could not afford to lose, to pressure recipients to take actions beyond the scope of the original bargain.

NFIB is controlling here because the IRA similarly leverages Medicare and Medicaid coverage to coerce BMS to submit to the Government’s mandates. *First*, the IRA threatens to remove *existing* coverage for *all* of BMS’s medicines unless BMS surrenders its rights regarding one product—Eliquis—just as Congress threatened to strip *all* of a State’s *existing* Medicaid funding to induce agreement to *new* conditions. Instead of withholding payments for Eliquis until BMS agreed to a lower one for that one medicine, Congress “threaten[ed] to terminate other significant independent grants.” *Id.* at 580. And just like in *NFIB*, the fact that Congress “styled” the Program as *part* of Medicare does not excuse the Government leveraging existing sources of federal funds to coerce BMS to comply with a new federal program. *Id.* at 582.

Second, the IRA improperly coerces BMS by threatening to take away BMS’s access to half of the U.S. prescription drug market. *Id.* at 581. The IRA thus gives BMS only an “illusory” choice, *Butler*, 297 U.S. at 71, because Congress knew that BMS and other pharmaceutical companies could not jeopardize their economic survival by refusing to deliver their medicines to the payor responsible “for almost half the annual nationwide spending on prescription drugs,” *Sanofi Aventis*, 58 F.4th at 699. Proving as much, Congress projected that the “tax” penalty would raise no revenue because it knew no company would pay it. *See supra* at 8. Sustaining the IRA would thus disregard the Supreme Court’s holding that funding recipients must have a choice “not merely in

theory but in fact.” *NFIB*, 567 U.S. at 581.

Third, the IRA “surpris[es]” BMS with new, “post-acceptance conditions” that “transform[]” the nature of the deal it entered “decades” earlier, *NFIB*, 567 U.S. at 581, 583–84. Congress expressly assured BMS and other pharmaceutical companies that the Government would “*not interfere*” in manufacturers’ pricing negotiations for Medicare, 42 U.S.C. § 1395w–111(i)(1) (emphasis added), but this new Program effects a bait and switch. The IRA does not just interfere with private pricing arrangements—it replaces them with compelled transfers at Government-set prices.

Accordingly, as in *NFIB*, the IRA does not offer BMS any “voluntary” choice, and is therefore unconstitutionally coercive.

Although the Affordable Care Act coerced *States* to abandon their constitutional rights, *NFIB*, 567 U.S. at 577–78, the IRA’s coercion of *private companies* to surrender their rights is unconstitutional for the same reasons. As the Third Circuit has observed, private entities no less than States can be subject to “‘economic dragooning’ and a ‘gun to the head’” when the Government threatens the “ruinous” “loss of federal funds.” *Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020) (quoting *NFIB*, 567 U.S. at 581–82). If anything, protection for private parties must be *more* robust for they, unlike States, lack the “political powers” and “institutional resources” to resist federal encroachment. *Koslow v. Pennsylvania*, 302 F.3d 161, 174 (3d Cir. 2002). For all of these reasons, the IRA puts BMS to an unconstitutional choice under *NFIB*.

2. The IRA threatens disproportionate penalties unless BMS surrenders its constitutional rights.

Framed as a condition, the IRA also violates the unconstitutional conditions doctrine, which “vindicates the Constitution’s enumerated rights by preventing the government from coercing people into giving them up.” *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). This doctrine, which “is based on the proposition that government incentives may be inherently coercive,” *Koslow*, 302 F.3d at 174, prohibits the Government from imposing conditions to eviscerate “the Fifth Amendment right to just compensation,” *Koontz*, 570 U.S. at 604, or to “compel[] a grant recipient to adopt a particular belief” or profess “the Government’s view on an issue,” *Agency for Int’l Dev.*, 570 U.S. at 218.

In the First Amendment context, compelling funding recipients “to profess a specific belief” is always impermissible, because such a regulation “by its very nature affects protected conduct outside the scope of the federally funded program.” *Id.* at 218. Indeed, the Supreme Court has “broadly rejected the validity of limitations on First Amendment rights as a condition to the receipt of a governmental benefit.” *Elrod*, 427 U.S. at 359 (plurality op.). In the Fifth Amendment context, the Government may condition benefits on surrendering private property rights only if the condition (1) has an “essential nexus” to the benefit and (2) is “rough[ly] proportiona[l]” to it. *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994); *see also Koontz*, 570 U.S. at 604; *Nollan v. Cal. Coastal Comm’n*, 483 U.S. 825, 834–37 (1987).

Under these principles, the IRA’s mandates bear all the hallmarks of an unconstitutional condition. The Government leverages *other* transactions to achieve its objectives, offers a “deal” BMS could not decline without jeopardizing its economic survival, and abuses the Government’s market power to compel BMS to express the Government’s viewpoint. This legislative pressure on BMS to abandon its fundamental rights violates the unconstitutional conditions doctrine.

To start, compelling BMS to publicly “agree” that Government-set prices are the “maximum fair prices” is not a lawful condition. The Government cannot use funding conditions to force recipients “to pledge allegiance to the Government’s policy.” *Agency for Int’l Dev.*, 570 U.S. at 220. The IRA’s requirement that BMS “agree” that an HHS-dictated price for Eliquis is the medicine’s “maximum fair price” is exactly that.

As for the Takings Clause, the IRA fails both *Dolan* requirements. Because the Program seeks to extract a favorable price for Eliquis by threatening funding for *other* BMS medicines, there is no “essential nexus.” *Dolan*, 512 U.S. at 386. Those other medicines are not even subject to the Program; they are simply being taken hostage. Where a condition is “unrelated” to the benefits being withheld, it rises to the level of “extortion.” *Nollan*, 483 U.S. at 837–38; *see also Harris v. McRae*, 448 U.S. 297, 317 n.19 (1980) (noting a “substantial constitutional question would arise if Congress had attempted to withhold all Medicaid benefits” based on exercise of constitutional right); *Cedar Point*, 141 S. Ct. at 2080 (rejecting argument that union “access” mandate was legitimate condition because it was not “germane to any benefit provided”).

Nor is the Government's threat to terminate coverage for all of BMS's medicines "rough[ly] proportiona[l]" to the IRA's requirement that BMS agree to the price set for Eliquis. *Dolan*, 512 U.S. at 391; *see also FCC v. League of Women Voters*, 468 U.S. 364, 400 (1984) (invalidating condition that required radio station receiving "only 1% of its overall income" from government grants to abstain "from all editorializing"). The Government's threat to use its leverage over pre-existing and unrelated payments for BMS's other medicines to demand favorable terms for Eliquis is a perfect illustration of a *coercive* condition, not a *proportional* one. *Cf. Compl., FTC v. Amgen, Inc.*, No. 23-cv-3053 (N.D. Ill. May 16, 2023) (FTC lawsuit to stop pharmaceutical merger based on prospect that merged entity would condition rebates for its portfolio of popular drugs on granting favored access to a single other product). Through the Program, the Government tries to condition BMS's access to an *entire market* on its "agreement" to sell *one product* (Eliquis) at a huge discount. This fails the second *Dolan* requirement.

No matter how the Government characterizes the Program, BMS cannot be coerced into "giv[ing]... up" its constitutional rights. *Koontz*, 570 U.S. at 604. And yet, this is precisely what the IRA attempts. In doing so, it violates the Fifth Amendment because it forces BMS to transfer Eliquis to third parties below fair market value, and it violates the First Amendment by compelling BMS to express the Government's viewpoint that the price it sets for Eliquis is the "maximum fair price." Awarding equitable relief for these constitutional violations will encourage BMS to continue researching and developing innovative medicines that will save American lives.

CONCLUSION

The Court should declare the IRA unconstitutional and enjoin Defendants from enforcing it against BMS.

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